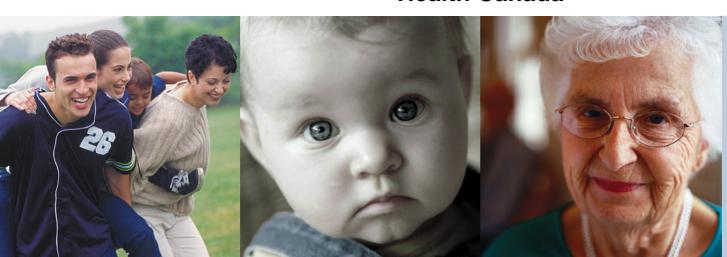
Regulatory Mentoring to Strengthen Capacity

A Case Study of the WHO-Canada-India Initiative

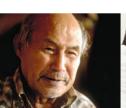
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WHO Vaccines Prequalification Programme

- WHO provides a service to UN purchasing agencies (e.g. UNICEF, PAHO)
- WHO provides independent opinion/advice on the quality, safety and efficacy of vaccines for purchase by assessing both the vaccine manufacturer and the National Regulatory Authority (NRA) of the manufacturing country
- Ensures that candidate vaccines are suitable for the target population and meet the specific needs of the program, reflected by the tender specifications (i.e. potency, presentation, labeling, shipping conditions, etc.)
- Ensures continuing compliance with specifications and established standards of quality
- Qualified manufactures & vaccines of assured quality listed on WHO web-site and countries purchase from this list







WHO Vaccines Prequalification Programme

Vaccines provided through the prequalification program must be produced in countries with an NRA that:

- Is independent and functional
- Meets all the critical indicators required for prequalification purposes following a WHO independent assessment
 - The status of the NRA is reassessed by WHO at regular intervals, usually every 4 years

Required Regulatory Oversight (critical indicators):

- Legislative and Regulatory Framework
- Market Authorization Process
- Post-market surveillance
- Lot release and laboratory functions
- Inspection capacity and strategy





WHO Assessment of NRAs of Canada and India

- <u>Jan 2007:</u> WHO assessed Canada's national regulatory system for vaccines. Assessment was successful in indicating that Canada's NRA for vaccines (BGTD) met all of WHO's critical indicators.
- <u>Aug 2007:</u> WHO conducted an assessment of the Central Drugs
 Standard Control Organization (CDSCO) of India, which revealed gaps in vaccine regulation
 - Assessment also led to the closure of three public sector vaccine manufacturers due to non compliance with Good Manufacturing Practices
 - Due to the key role India plays as a vaccine manufacturer and supplier (7 vaccine manufacturers producing essential vaccines), immediate action was needed to help bring the vaccine regulatory system of India in line with WHO requirements







- WHO recommended that CDSCO seek the collaboration and support of an assessed functional NRA with recognized training experience and international credibility in the regulation of vaccines, to help enhance the vaccine regulatory capacity within India
- It was agreed by WHO and CDSCO to approach Health Canada and request that it provide this support
 - Health Canada, via the Biologics and Genetic Therapies
 Directorate agreed to provide this support





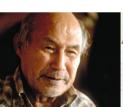
Process

- <u>April 2008:</u> BGTD & WHO experts visited India to further assess gaps and identify key needed components of a training programme. This visit revealed that:
 - The Ministry of Health and Family Welfare, Drugs Controller General and staff of CDSCO were deeply committed to this mentoring initiative and willing to invest the time and resources needed to enhance India's vaccine regulatory capacity;
 - The struggles being faced by CDSCO with respect to vaccine regulation were ones that many regulators worldwide, including Health Canada have and continue to face, including:
 - A regulatory system which includes responsibilities at both the federal and regional level
 - Recruitment and training of review and other regulatory staff
 - Overarching legislation which may require modernization
 - Lack of specific guidelines and standard data criteria for manufacturers and lack of standard operating procedures for regulatory staff
 - Need to ensure proper documentation of review and regulatory activities (implementation of electronic systems)
 - Need to enhance harmonization and collaboration with international regulatory partners





- <u>Summer 2008:</u> Four Indian NRA delegates participated in a two-week training course on vaccine regulation (in Ottawa)
- This comprehensive course attempted to cover all aspects of vaccine regulation from the Canadian perspective including:
 - Legislation and Regulations
 - Submission Processing and Screening
 - Data requirements in CTD format
 - Review of manufacturing, non-clinical and clinical data
 - Statistical evaluation
 - Lot Release testing
 - GMP and product specific inspections
 - Post-market surveillance
 - Patents and Intellectual Property
 - Cold Chain maintenance
- At the conclusion of this training it was determined that more enhanced training on submission processing and the review of manufacturing, non-clinical and clinical data was required to be delivered to a broader group of reviewers at CDSCO





Additional Effort

- In addition to participating in the training,
 CDSCO worked diligently to:
 - Fill vacancies amongst review positions
 - Implement electronic and other data management systems
 - Draft guidance documents and Standard Operating Procedures





Outcome

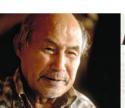
- In April 2009 a follow-up assessment of CDSCO by WHO was positive, finding that they met critical indicators
- Agreed however that further capacity building support would be helpful
 - CDSCO and BGTD agreed to conduct a parallel review of a vaccine submission. This was initiated in May 2009 and is ongoing





Key Messages

- Due to emerging challenge of regulating new vaccines, NRAs of developing countries with a vaccine
 manufacturing sector require new skills and expertise to assess data and dossiers (manufacturing,
 preclinical and clinical data, etc.)
- Health Canada in cooperation with WHO is assisting other NRAs in regulatory capacity building process (e.g. India)
- Health Canada's regulatory capacity building for the WHO's vaccines prequalification program contributes to the global vaccine security and public health safety worldwide
- During the regulatory capacity building, Health Canada is encouraging harmonization with other NRAs (e.g. to use ICH's CTD formats), as it contributes to the work-sharing process among the NRAs
- Health Canada is also encouraging regional cooperation among the NRAs, as a means to strengthens regional regulatory capacity
 - Health Canada has supported the Vaccines Working Group of the Pan-American Network on Drug Regulatory Harmonization (PANDRH) in developing a document on harmonized requirements for the licensing of vaccines in the region.
 - Health Canada is participating, at WHO request, in the African Vaccine Regulatory Forum, an initiative to encourage cooperation amongst African nations.







Thank you/Merci!

